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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,818	01/09/2002	David R. Elmaleh	MGA-004.25	2433

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FOLEY HOAG, LLP  
PATENT GROUP, WORLD TRADE CENTER WEST  
155 SEAPORT BLVD  
BOSTON, MA 02110

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/530,818

**Applicant(s)**

ELMALEH ET AL.

**Examiner**

D. L. Jones

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2004 and 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1616

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the RCE (request for continued examination) filed 1/26/04. In addition, the Examiner acknowledges the amended filed 11/26/03 wherein claims 1, 8, 9, 11, and 12 were amended; and claims 2-7 and 13-18 were canceled.

**Note:** Claims 1 and 8-12 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to imaging agents and a method of imaging thereof wherein the imaging agent comprises a PET radionuclide ( $^{18}\text{F}$ ,  $^{68}\text{Ga}$ ,  $^{62}\text{Cu}$ , and radioactive isotopes of iodine) and a targeting moiety selected from cells, colony stimulating factors, platelet factor 4, growth factors, cytokines, interferon, tumor necrosis factors, cellular sources of energy for metabolic active plaque formation, lipids, lipid receptors, and components of clotting.

## **RESPONSE TO APPLICANT'S AMENDMENT**

3. The Applicant's arguments filed 11/25/03 to the rejection of claims 1-4 and 6-17 made by the Examiner under 35 USC 102, 103, 112, and/or double patenting have been fully considered and deemed persuasive because Applicant has amended the claims to overcome the rejection and submitted an acceptable terminal disclaimer.

Art Unit: 1616

## **NEW GROUNDS OF REJECTIONS**

### **112 Second Paragraph Rejections**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8-12: The claims as written are ambiguous because of the phrase 'radionuclide being associated with a targeting moiety' (see independent claims 1, 9, and 12). In particular, is Applicant saying that the targeting moiety is radiolabeled? The claim as written given the broadest interpretation reads on a directly radiolabeled targeting moiety and an indirectly labeled targeting moiety (i.e., radiolabeled-chelate/ligand-targeting moiety). Please clarify so that one may readily ascertain what is being claimed.

### **103 Rejections**

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

7. Claims 1 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calenoff (US Patent No. 6,025,477) in view of Conti et al (US Patent No. 6,331,287) and in further view of Fritzberg et al (US Patent No. 5,175,343).

**Calenoff** discloses atherosclerotic plaque specific moieties and uses of the complexes for imaging atherosclerotic plaque (see entire document, especially, abstract). In addition, Calenoff discloses the following: (1) the targeting moiety may be labeled with a detectable marker and that the choice of the marker selected is dependent upon the application and a skilled practitioner in the art is capable of readily determining the marker (column 8, lines 8-22; column 11, lines 4-14). (2) Possible markers include opaque x-ray isotopes, paramagnetic ions, or chelates of a paramagnetic ion (column 15, lines 1-4). (3) Such radioisotopes include I-123, I-125, I-128, I-131, gallium-68, and copper (II) [column 15, lines 5-18]. (4) The imaging agents may be used for imaging atherosclerotic plaque. The method of imaging involves containing the atherosclerotic plaque to be imaged with a reagent that binds specifically to the atherosclerotic plaque antigen and determining the reagent bound thereto by imaging (column 15, lines 22-45 and 52-59; column 16, lines 8-28; columns 38-39, section VI). (5) Imaging may be performed through any methods known to one skilled in the art. Possible methods include x-ray, CAT scan, PET scan, NMR, and fluoroscopy (column 16, lines 29-32). (6) Possible reagents include antibodies and enzymes (column 16, lines 33-68). While Calenoff disclose various isotopes (i.e., copper, iodine, and gallium) that may be used with their invention, the reference fails to specifically

Art Unit: 1616

disclose fluorine for imaging and a kit containing the radionuclide-targeting moiety complex.

**Conti et al** disclose that imaging agents may be labeled with positron emitting radioisotopes such as 11-carbon and 18-fluorine (see entire document, especially, column 3, line 8-9). It should be noted that Conti et al is cited only for its teachings that 18-fluorine is a label for PET imaging.

**Fritzberg et al** disclose labeled targeting agents that may be used for diagnostic and therapeutic purposes (see entire document, especially, abstract). In particular, column 17, line 40, through column 19, line 4, is directed to generating a kit for imaging. The kits will generally be used in hospitals, clinics, and other facilities (column 16, line 42-66). It should be noted that Fritzberg et al is relied upon for its teachings of the importance of generating a kit.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Calenoff using the teachings of Conti et al and use 18-fluorine for PET imaging because Calenoff discloses a plaque targeting component and radionuclide complex wherein the radionuclide is a PET imaging nuclide may be conjugated. In addition, Calenoff discloses various radionuclides such as I-123, I-125, I-128, I-131, gallium-68, and copper (II) that may be conjugated to the targeting moiety. Also, Calenoff discloses that the imaging may be performed by PET scan. Hence, a skilled practitioner in the art would recognize that the type of imaging method requires the appropriate radionuclides. Hence, since fluorine-18 is a well known PET imaging agent as indicated by Conti et al and because Calenoff discloses that the

Art Unit: 1616

detectable marker (radionuclide) is a matter of choice to one skilled in the art and may be selected from the various nuclides used for x-ray, CAT scan, PET scan NMR, and fluoroscopy, one would be motivated to use 18-fluorine, a common PET isotope. In particular, column 3 (lines 8-9) of Conti et al discloses that PET imaging agents may be labeled with 18-fluorine.

Since both Calenoff and Conti et al encompass PET isotopes for imaging agents, it would be obvious to one of ordinary skill in the art that 18-fluorine is encompassed in the invention of Calenoff. Thus, the references may be considered to be within the same field of endeavor and their teachings may be combined.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit containing the radionuclide and targeting complex. Thus, one would have been motivated to combine the teachings of Calenoff, Conti et al, and Fritzberg et al in order to generate a kit because of the ever present need for such kits in hospitals, clinics, and other medical facilities. In addition, a skilled artisan would be able to apply the procedures for generating a diagnostic kit found in Fritzberg et al to accommodate the radionuclide-targeting moiety complex.

Since all the references are directed to targeting agents that may be labeled for diagnostic purposes, the references may be considered to be within the same field of endeavor. Hence, the references are combinable.

Art Unit: 1616


**COMMENTS/NOTES**

8. Applicant is respectfully requested to correct the spelling of platelet in independent claims 1 (line 6), 9 (line 7), and 12 (line 7).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

April 15, 2004